

DEC 1 2 2001

EXHIBIT 2

K013807

CANÈ S.r.l.  
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Contact: Mario Canè, President  
October 9, 2001  
Rev December 5, 2001

**510(k) Summary of Safety and Effectiveness**

**1. Identification of the Device:**

**Proprietary-Trade Name:** Microjet *Quark* Model U-100

**Classification Name:** LZG

**Common/Usual Name:** Pump, Infusion, Insulin

**2. Equivalent legally marketed devices** This product is similar in function to the Dana Diabecare infusion pump, K001604.

**3. Indications for Use (intended use)** The portable Quark infusion device has been designed only for use in subcutaneous infusion for insulin infusion therapy. Canè S.r.l. declines all responsibility for the administration of drugs in treatments and with methods other than the above.

**4. Description of the Device:** Microjet Quark U-100 is an ambulatory insulin pump using syringe, battery powered and available to employ 2 ml syringes. A special micromotor acting the mechanical parts transforming the rotating movement of the motor into a linear movement of the slider which determines the moving of the syringe piston. The characteristics of the pump working allow to administer insulin according to two infusion ways: the first one, **basal rate**, ensure an insulin basal feed within 24 hours, the second one, **bolus**, allows to administer insulin additional doses and finds its most common use at meal-time. During the basal rate, the motor is driven with impulses at regular intervals by mean of a particular electronic circuit and the infusion is effected by administering of small quantities repeated over the time. The programmed insulin quantity is distributed with 304 administrations within 24 hours, one every 4 minutes and 44 seconds. The bolus is delivered with fast insulin administrations of 0,5 International Units (UI) each time, with intervals of 10 seconds pauses. The administration of the insulin basal quantity is programmed operating on a specific selector allowing an accurate delivery of insulin, depending on the various daily needs. Insulin delivery as bolus is programmed using a specific button. The pump starts delivering insulin in basal speed to the selected value. It remains operating until, by mean of manual command, the administration of the bolus is primed; after it returns automatically to work again. The pump is equipped of safety systems, acoustic signals for different operating functions and acoustic alert signals in the event of irregular working.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench, FMC, and user testing indicates that the new device is as safe and effective as the predicate device.

6. **Substantial Equivalence Chart**

Characteristic	Dana Diabecare, K001604	Microjet <i>Quark</i>
Intended Use:	Insulation infusion therapy, subcutaneous.	SAME
Physical characteristics:		
Power Source	2 A.A. batteries	Varta® 30PXL, lithium 6V (6 weeks life)
Size	75 x 45 x 19 mm	110 x 60 x 20 mm..
Weight	61 gr (battery included)	135 gr. (battery included).
Capacity	3ml (300 units)	2 ml (200 units)
Insulin concentration	U-100 (default)	SAME
Warranty:	4 years	1 year

7. **Conclusion**

After analyzing both bench and user testing data, it is the conclusion of CANE S.r.l. that the Microjet Quark is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 12 2001

Cane SRL  
C/O Ms. Daniel Kamm  
Regulatory Engineer  
Kamm & Associates  
P.O. Box 7007  
Deerfield, Illinois 60015

Re: K013807

Trade/Device Name: Microjet Quark, Model U100  
Regulation Number: 880.5725  
Regulation Name: Pump, Infusion, Insulin, LZG  
Regulatory Class: II  
Product Code: LZG  
Dated: November 14, 2001  
Received: November 15, 2001

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

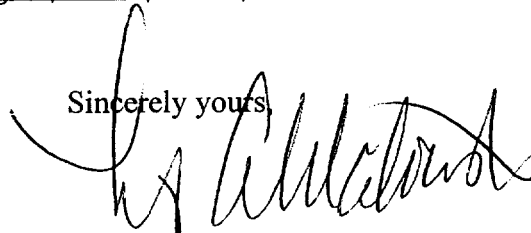
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**j) Indications for Use**

510(k) Number 13013807

**Device Name:** Microjet *Quark* ambulatory infusion pump

**Indications for Use:** The Microjet Quark U-100 ambulatory infusion pump has been designed only for use in subcutaneous infusion of insulin for the treatment of diabetes mellitus. (Home use, prescription device)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

OR

Over the Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)

*Patricia Cucurite*

(Division Sign-Off)

Division of Dental, Infection Control,

and General Hospital Devices

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